HEALTH INSURANCE REFORM/Medical Necessity and External Review

SUBJECT: **Patients' Bill of Rights Act . . . S. 1344. Frist amendment No. 1238 to the Nickles amendment No. 1236.**

ACTION: AMENDMENT AGREED TO, 52-48

SYNOPSIS: As introduced, S. 1344, the Patients' Bill of Rights Act, contains the text of S. 6, a health insurance regulation bill proposed by Senator Kennedy and other Democrats. The bill: will regulate the structure and operation of all health insurance products at the Federal level; will impose extensive mandates on consumers, health insurers, and employers; and will create new rights to sue employers and insurers for unlimited compensatory and punitive damages. As estimated by the Congressional Budget Office (CBO), this Democratic plan will cause insurance premiums to rise by an average of 6.1 percent (which will be in addition to any increases from inflation or other causes). The 6.1-percent cost increase, which will total $72 billion over 5 years, will cause approximately 1.8 million Americans to lose their health insurance coverage.

The Nickles amendment would provide that this Act would not apply to any group health plan if its application in a year caused (or would cause, as determined by a certified actuary) that plan's premiums to rise by more than 1 percent, and it would not apply to any group health plan if it caused (or would cause, as projected by the National Association of Insurance Commissioners) a decrease in 1 year of more than 100,000 in the number of privately insured Americans.

The Frist amendment would strike the section of the Kennedy bill regarding appeals of adverse coverage decisions and would substitute alternative provisions. The Kennedy bill would first define the term "medical necessity" to mean whatever was "consistent with generally accepted principles of professional practice." It would then require all group and individual health plans to pay for any "medically necessary" treatment an attending physician prescribed for a covered benefit. Further, it would prohibit plans from being involved in deciding the manner and setting in which treatment was given. The Kennedy bill would also require specific grievance procedures and internal and external appeal processes to be implemented to resolve any disputes on coverage decisions, medical or otherwise. Only a doctor or health care professional could make a decision on an internal or external appeal, including a decision on any legal or administrative matter. Independent external appeal entities would need to have either State or Federal

(See other side)

YEAS (52)

Republicans (52 or 94%)		Democrats (0 or 0%)
Allard	Hutchison	
Ashcroft	Inhofe	
Bennett	Jeffords	
Bond	Kyl	
Brownback	Lott	
Bunning	Lugar	
Burns	Mack	
Campbell	McCain	
Cochran	McConnell	
Collins	Murkowski	
Coverdell	Nickles	
Craig	Roberts	
Crapo	Roth	
DeWine	Santorum	
Domenici	Sessions	
Enzi	Shelby	
Frist	Smith, Bob (I)	
Gorton	Smith, Gordon	
Gramm	Snowe	
Grams	Specter	
Grassley	Stevens	
Gregg	Thomas	
Hagel	Thompson	
Hatch	Thurmond	
Helms	Voinovich	
Hutchinson	Warner	

NAYS (48)

Republicans (3 or 6%)	Democrats (45 or 100%)	
Abraham	Akaka	Kennedy
Chafee	Baucus	Kerrey
Fitzgerald	Bayh	Kerry
	Biden	Kohl
	Bingaman	Landrieu
	Boxer	Lautenberg
	Breaux	Leahy
	Bryan	Levin
	Byrd	Lieberman
	Cleland	Lincoln
	Conrad	Mikulski
	Daschle	Moynihan
	Dodd	Murray
	Dorgan	Reed
	Durbin	Reid
	Edwards	Robb
	Feingold	Rockefeller
	Feinstein	Sarbanes
	Graham	Schumer
	Harkin	Torricelli
	Hollings	Wellstone
	Inouye	Wyden
	Johnson	

NOT VOTING (0)

Republicans (0)	Democrats (0)

EXPLANATION OF ABSENCE:
1—Official Business
2—Necessarily Absent
3—Illness
4—Other

SYMBOLS:
AY—Announced Yea
AN—Announced Nay
PY—Paired Yea
PN—Paired Nay

certification. If two or more entities received certification, then the health plan would select which entity it would use. The health plan would have to pay for the costs of any external appeal. The external appeal entity would hire an independent physician to make a determination. A decision would be binding on a health plan but could be appealed in court by a patient. The Frist amendment would enact provisions that would differ from the Kennedy bill provisions in two main respects. First, instead of enacting a Federal definition for the term "medical necessity," it would enact criteria for internal and external reviewers to consider. Those criteria would make them determine which treatments, if any, were best and most appropriate, rather than just deciding (as proposed by the Kennedy bill) whether a proposed treatment was generally accepted as a treatment for the medical problem (practices vary widely by region, and many common, generally accepted practices are known by peer-reviewed studies to be neither necessary nor appropriate). More specifically, in the external review process, the Frist amendment would require an independent reviewer to "make an independent determination based on the valid, relevant, scientific, and clinical evidence to determine the medical necessity, appropriateness, experimental, or investigational nature of the proposed treatment" and to "take into consideration appropriate and available information, including: any evidence-based decision making or clinical practice guidelines used by the group health plan or health insurance issuer; timely evidence or information submitted by the plan, issuer, patient or patient's physician; the patient's medical record; expert consensus; and medical literature." The second major difference from the Kennedy bill is that the Frist amendment would limit the internal and external appeals disputes that could be considered to disputes regarding medical necessity and appropriateness and to denials of treatments based on their experimental or investigational nature. Non-medical disputes, such as legal or administrative disputes, would continue to be handled by insurance regulators.

Those favoring the amendment contended:

The main problem that is occurring in managed care today is that medical decisions are sometimes being made by non-medical personnel based on cost considerations rather than on what is needed by patients. Both the Kennedy bill and the Republican bill address this problem. The pending Frist amendment to the Kennedy bill would substitute the Republican approach, which is far more focused and which would prove far more beneficial for patients.

Both bills would set up grievance and internal and external appeals processes as the major part of their answer to this problem. Both bills, in their internal and independent external appeals processes, would require doctors to make decisions on any medical questions that were raised. Both bills would require insurers to pay any costs of the external appeals entities that are created, and both bills would require appeals entities to be licensed by the Federal Government or State governments. Under the Republican bill, an insurer would be permitted to pick which entity would be in charge of picking a doctor to hear an external appeal. Democrats have said that this provision is horrendous. However, we note that under the Kennedy bill, if more than one entity were available to be hired, then the insurer could choose which entity to hire. In practical effect, the Kennedy bill is thus exactly the same as the Republican bill on this point. It is true that the Kennedy bill would enact a more elaborate bureaucratic structure for its appeal processes, but otherwise there is not that great a difference.

However, how those similar proposed processes would be used would differ significantly in two important respects. First, the Kennedy bill would require doctors, when they were deciding whether treatment should be approved, to use an expansive definition of the term "medical necessity" that would force them to approve ineffective and even dangerous medical procedures. Specifically, it would require them to approve any treatment for a covered benefit if that treatment was "generally accepted." Medical practices vary widely from region to region, and even from county to county, and many practices that are generally accepted are out of date, are less effective than other practices, are ineffective, or are even dangerous. In every one of these cases, if a doctor proposed a treatment, the appeals process would have to approve it, and the patient would not receive the necessary, appropriate care. Most medicine that is being practiced today did not even exist 20 years ago. The field is changing at an exponential rate. The huge number of advances that are being made keep the practice of medicine in such flux that it is impossible to develop a national consensus on what is generally accepted. In truth, because practices vary so widely, it is fair to say that nearly all treatments are generally accepted. For instance, the Washington Family Physicians Collaborative Research Network studied how physicians treat bladder infections for adult women, which is the second most common problem seen in a physician's office. It asked 137 physicians how they would treat a 30-year-old woman with a 1-day history of an uncomplicated urinary tract infection, and it got 82 different treatment options in response. Under the Kennedy bill, every one of those options would have to be approved, no matter how ineffective or expensive, even if the insurance company had peer-reviewed, carefully done studies that proved that one of those options was by far and away the best option to use. Only a small percent of medical practice reaches that gold standard of proof of effectiveness--most medical practices in use have not had that kind of validation. In some cases, regional variations in treatment develop that a health insurance company would be justified in attempting to change. For instance, studies have shown that the mastectomy rate for treating breast cancer in South Dakota is 30 times or more higher than rates in other areas of the country, where less radical surgery is used with the same effectiveness. In other cases, medical "fads" seem to take hold. At one time, tonsillectomies were performed almost as a matter of course on children, even when there was no indication of a need. Doctors would offer family packages, taking the tonsils out of all of the children in a family in one day. A current fashionable operation is to insert tubes in children's ears to treat infections.

The American Medical Association recently reported that in 21 percent of the cases those operations were unjustified and that in 41 percent of the cases the justification was doubtful. Sometimes, the problem is that doctors are just not keeping up with new advances. For instance, a 1997 study found that only 21 percent of elderly patients were treated with beta blockers after they had heart attacks, even though there is strong proof that mortality rates decline by 75 percent or more if they receive such treatment. Interestingly, the patients most likely to get beta blockers were in managed care plans; under the Kennedy bill, if an insurance company wanted to prescribe beta blockers instead of some other treatment, it would not have a say in the matter. It would be bound by whatever ineffective treatment the attending doctor prescribed. Yet another problem with the idea of approving any generally accepted medical practice is that some generally accepted practices are clearly frivolous. In some areas, it is common to prescribe cosmetic surgery, music therapy, art therapy, and other such treatments in order to improve the health of patients. Under the Kennedy bill, insurance companies could end up having to pay for such items as art work to cheer up their patients. We imagine this expansive definition might have an effect on insurance premiums.

The Republican bill, on the other hand, would set up a process that would guarantee that patients would get the medical care to which they were entitled, and that they would get the best possible medical care to which they were entitled. Under the Republican bill, if a doctor proposed a treatment for a covered benefit and if the insurer disagreed that the treatment was medically necessary and appropriate, an internal appeal would first be held. A doctor with the necessary specialized training in the area would review the decision. If that doctor believed the treatment was unnecessary or inappropriate, or that another treatment was better, then the patient could make an external appeal. Another expert doctor, who would be totally independent from the insurer, would then review the case. In both instances, the doctors reviewing the case would not merely decide whether the proposed treatment was one of many generally accepted treatments for the particular problem being addressed. Instead, they would be required to make an independent determination based on the valid, relevant, scientific, and clinical evidence to determine the medical necessity, appropriateness, and experimental or investigational nature of the proposed treatment. In some cases, they might decide that a doctor's decision to perform a Caesarean section was just for the convenience of that doctor, and the treatment might be denied (the Centers for Disease Control reports that hundreds of thousands of unnecessary Caesarean sections are performed each year). Such operations pose higher risks for women than natural childbirth, but, under the Kennedy bill, a doctor's choice to take those risks with women's health could not be questioned.

The other huge difference between the Kennedy bill and the Republican bill in the proposed review processes is that the Kennedy bill would go far beyond deciding medical questions. It would have doctors reviewing any denials of proposed treatments that had nothing to do with questions of medical necessity or appropriateness. Questions that are now routinely and expertly handled by State and Federal insurance regulators, working with their expert legal and accounting counterparts in the insurance companies, would be thrown into these review processes to be decided by doctors. This arrangement would create chaos. Terms of contracts would become meaningless as they were modified by uninformed decisions of medical doctors. Just as lawyers and accountants should not be practicing medicine without a license by making decisions on medical necessity, doctors should not be practicing law or accounting without licenses. The Republican bill, in contrast, stops lawyers and accountants from practicing medicine, and then it stops. It does not give doctors the lawyers' and accountants' jobs too.

Some Senators have suggested that the external review process in the Republican bill is tainted because it would allow the insurance company to pick the licensed independent entity that would pick the independent expert doctor to conduct the review, and because it would require the insurance company to pay the costs of the review. This suggestion strikes us as rather odd, considering it is the same arrangement as is in the Kennedy bill. In both cases, we believe that independence is guaranteed by the licensing process and by the fact that the actual reviewer would be picked by the entity, not the company. Neither the Federal Government nor any State governments are going to license entities that are not truly independent, and the fact that insurers pay the bills will not affect their independence any more than a State paying a public defense lawyer to protect someone it is prosecuting affects that lawyer's spirited defense of his or her client.

The Republican plan would set up a fast, non-bureaucratic, independent review process under which doctors would quickly decide if a group health plan's denial of treatment was justified based on the specific medical circumstances of each case. It is clearly superior to the Democratic proposal which would unwisely attempt to enact a uniform definition of medical necessity, thereby putting patients' health and lives at risk, and which would put doctors in charge of making legal and accounting decisions as well as medical decisions. The Republican plan would fix the major problem in managed care today; the Kennedy plan would make it worse. We strongly urge our colleagues to support the Republican plan by voting in favor of this amendment.

Those opposing the amendment contended:

The Frist amendment would enact the Republican bill provisions on the review of insurance plan denials of medical treatment. Those provisions have several serious problems. First, they do not guarantee that the external reviews will be truly independent. The Republican bill would allow a health maintenance organization (HMO) to hire any independent entity it wished to conduct its reviews. That entity could then hire a doctor who worked for the HMO to conduct the review. The only requirement would be that

the doctor hired could not have any direct connection to the case. That requirement is pretty weak, and we think that it would result in people being denied fair reviews. Their only remaining recourse would be to go to court. Second, there is nothing in the Republican bill that would prohibit an "independent" entity from having a longstanding professional or financial relationship with an HMO that might hire it. Again, allowing this type of relationship would likely result in very unfair reviews. Third, we believe that the wording of this amendment would allow insurance companies to put definitions of "medical necessity" into their contracts that would make it impossible for reviewers to overturn coverage denials. We understand that our Republican colleagues say that they do not have that intent, and we understand that independent legal analyses have been conducted that say that we are wrong, but we believe that the plain wording of the Republican bill would require reviewers to accept each plan's definition. The definition of "medical necessity" has been developed over the past 200 years in case law. It has not been codified until now; putting it into law would prevent insurance company efforts to try to change it. The Kennedy bill, by clearly codifying the well understood definition of medical necessity, by putting doctors in charge of deciding which treatments met that definition, and by setting up a truly independent process to stop health insurance companies from interfering with those decisions, would enact the needed protections. The Frist amendment would gut those protections and would substitute the empty reforms contained in the Republican bill. The main effect of those so-called reforms would be to protect insurance company profits instead of patients' lives. This vote may be the most critical in the entire debate. We urge our colleagues to reject the Frist amendment.